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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,780	05/03/2002	Yoshio Okubo	SDF-02-8	5042
31764	7590	02/02/2005	EXAMINER	
LAW OFFICE OF STUART D. FRENKEL, P.C. 3975 UNIVERSITY DR., STE. 330 FAIRFAX, VA 22030			YOUNG, MICAH PAUL	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 02/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/069,780	Applicant(s) OKUBO ET AL.	
	Examiner Micah-Paul Young	Art Unit 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on 14 April 2004.

2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 1-13 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
       Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
       Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
       a) ☐ All    b) ☐ Some \* c) ☐ None of:  
           1. ☐ Certified copies of the priority documents have been received.  
           2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
           3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
       Paper No(s)/Mail Date \_\_\_\_\_

4) ☐ Interview Summary (PTO-413)  
       Paper No(s)/Mail Date. \_\_\_\_\_

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

**Acknowledgement of Papers:** Amendment/Response dated 04/14/04

#### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

1. Claims 1-3 and 5-7 are rejected under 35 U.S.C. 102(a) as being anticipated by Saferstein et al (USPN 6,086,856 hereafter '856). The claims are drawn to an oral formulation comprising a medicament and a foaming agent. The claims also recite a method of administration.

'856 discloses a system for delivering a foaming oral composition. The foaming composition is delivered via an air driven foaming device (claims) container. The aqueous foaming oral formulation comprises polyethylene glycol, polysorbate and sodium lauryl sulfate (col. 7, lin. 1-col. 9, lin. 34). The composition further comprises drugs and viscosity agents such as xanthan gum (*Ibid.*). These disclosures render the claims anticipated.

#### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4, and 8-13 rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures Saferstein et al (USPN 6,086,856 hereafter '856). As disclosed above '856 discloses an oral foaming composition comprising polyethylene glycol, polysorbate and sodium lauryl sulfate. The reference however does not disclose the exact mixtures of claims 4 and 8. However the reference discloses a mixture of sodium lauryl sulfate and polysorbate in one formulation (example 3).

It is the position of the examiner that such combination as recited in claims 4 and 8 would be well within the level of skill in the art. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. *See In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Regarding claims 9, 13 it is the position of the examiner that such limitations do not impart patentability on the claims. The general conditions of the claims are met by the prior art including the aqueous forming agents such as polyethylene glycol, polysorbate and sodium lauryl sulfate. Applicant is reminded that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various compositions having various amounts

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of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

Regarding claim limitations drawn to the foam being re-liquified, it is the position of the examiner that these limitation represent a future intended use of the product and do not impart patentability on the presently claims invention. Any aqueous foam product will eventually re-liquify depending upon the components. The prior art discloses an identical product having identical components (foaming agents, pharmaceutical agents and viscosity agents). Also the final viscosity of the foam can be manipulated and determined through routine experimentation by one of ordinary skill in the art. Barring a showing of unexpected results the claims will remain obviated by the prior art disclosures.

With these things in mind one of ordinary skill in the art would have been motivated to combine the foaming agents disclosed by '856 in order to impart stability ensure proper delivery of the active agents. It would have been obvious to combine the foaming agents in such a way with an expected result of a foaming oral composition capable of delivering hygienic agents to the mouth.

#### ***Response to Arguments***

4. Applicant's arguments filed 4/14/04 have been fully considered but they are not persuasive. Applicant argues that:

- a. The composition of '856 is not for internal use and does not anticipate the claims

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b. Since the active ingredient of the present claims is intended to be swallowed, the '856 reference does not anticipate.

5. Regarding argument a., it is the position of the examiner that the '856 reference does in fact teach a composition for internal use. The reference teaches that the foamed composition can be used as a mouthwash or rinse. The mouth by definition is the beginning of the gastrointestinal tract and inside of the body. That the composition is later removed from the cavity has no bearing on the disclosures. The internal use language is merely an intended use for the composition, which has been disclosed in detail in the '856 reference. In response to applicant's argument that the composition is for internal use, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Barring a showing of unexpected results the claims will remain rejected by '856.

6. Regarding argument b., it is the position of the examiner that the swallowing of the composition has no bearing on the instant claims. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the composition is swallowed) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir.

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1993). Barring a showing of unexpected results and showing of criticality, the claims will remain rejected by the prior art.

***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young  
Examiner  
Art Unit 1615

MP  
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